REMARKS

Claims 1-7 and 11-16 are pending in the application. Applicants have amended claims 1 and 7, and added new claims 12-16. The amendments to claims 1 and 7 simply clarify the injectable nature of the claimed compositions. New claims 12 and 13 are supported in the specification at page 3, line 26-page 4, line 2. New claims 14 and 16 are supported in the specification at page 7, line 25-page 8, line 3. New claim 15 is supported in the specification at page 4, lines 17-23. Applicants submit that claims 12-16 are patentable for the same reasons as claims 1-7 and 11 and that none of the claim amendments add new matter.

In response to the rejection of claims 1-5, 7, and 11 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,939,974 (Valentini), and the rejection of claim 6 under 35 U.S.C. § 103(a) as allegedly obvious over Valentini in view of U.S. Patent No. 6,187,742 (Wozney), Applicants submitted evidence, in the form of a Declaration under 37 C.F.R. §1.132 from a scientist with first hand knowledge of the Valentini compositions, that none of the compositions described in Valentini were, or could be, injected into a patient. In a Final Office Action issued August 1, 2003, the Examiner maintained the §103(a) rejections in spite of this evidence, stating merely that "[t]his is not agreed." (Office Action, 8/1/03, page 2.) In an Advisory Action issued November 12, 2003, the Examiner argues that he need not provide any evidence to rebut the showing made by Applicants that the prior art compounds cannot be injected into a patient. (Advisory Action, 11/12/03, page 2.)

Applicants again traverse the rejections under 35 U.S.C. §103(a). The compositions described by Valentini are not injectable. Moreover, neither Valentini nor

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Wozney provide the required motivation to modify the Valentini compositions to render them injectable—as claimed by Applicants. Because the prior art does not suggest this modification, it also fails to teach a critical limitation of the pending claims—that the compositions must be injectable through the skin of a patient. As a result, the rejections under 35 U.S.C. § 103(a) must be withdrawn.

The Examiner has repeatedly urged that the intermediate compositions of Valentini—which constitute a thick paste—can be injected through a device like a caulking gun. The Examiner contends that the injectability of a thick paste is "known to anyone who has done home repairs." (Advisory Action, 11/12/03, pages 2-3). Applicants respectfully submit that the understanding of one "who has done home repairs" is not the appropriate standard for this analysis. Instead, the question of whether the prior art renders the claimed injectable compositions obvious should be determined by the understanding of one of skill in the art to which the invention pertains—i.e., pharmaceutical drug delivery—not home repairs. Manual of Patent Examining Procedure, Section 2144.03.

More importantly, the only evidence in the record on this issue, the Declaration of Dr. Hyun Kim, a scientist with personal knowledge of the both claimed compositions and the prior art compositions, demonstrates that the prior art compounds cannot by delivered to a patient by injection. The Examiner cannot overcome this evidence merely by citing to general knowledge of home repairs. Caulking guns are not used for delivery of pharmaceutical compounds to patients.

The Kim Declaration (¶ 9) states that the prior art compositions comprise a thick, slurry-like material containing HYAFF® and a pore former (citing Valentini at col. 8, line

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32) and indicates (¶¶ 9-11) that the large pore size of the Valentini compositions renders them uninjectable. Examiner disputes this evidence, contending that the "liquids do not have porosity." (Advisory Action, 11/12/03, page 2). Examiner states that this "is so well known that non-technical persons are familiar with the concept." (Id.) However, the issue is not whether liquids have pores, but whether the compositions of Valentini have pores, and whether the size of these pores prevent injection through the skin of a patient. The Examiner's argument directly contradicts Valentini itself—at col. 8, line 32—wherein it specifically states that the intermediate composition contains a pore former. It also contradicts the evidence provided by Dr. Kim, in his Declaration.

Moreover, the Examiner has provided no evidence to support his opinion that the compositions of Valentini do not have pores. An artisan skilled in the field of pharmaceutical delivery vehicles would understand that there is a continuum between liquids and solids, and there are many substances described as "liquid" that may share properties, such as porosity, with solids. The compositions of Valentini are examples of these "liquid" or "liquid-like" materials. The only evidence in the record as to the porosity of the Valentini compositions is in the Valentini disclosure and the Kim Declaration. The Valentini specification describes the addition of pore formers of 100-600 μm in diameter. (Co. 8, line 44.) The Kim Declaration (¶ 11) demonstrates that compositions with pores of this size are not injectable. Thus, contrary to the Examiner's assertions, the evidence makes it clear that the compositions of Valentini do contain pores and that these pores render the intermediate compositions of Valentini uninjectable.

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Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103(a) because the compositions of Valentini are not injectable and there was no motivation or suggestion in Valentini and/or Wozney to make the claimed injectable compositions. Applicants further request immediate allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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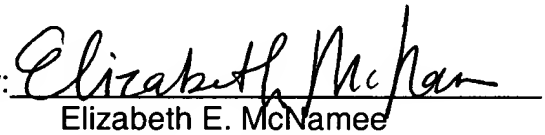
Dated: January 30, 2004

By: 
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